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REMARKS

Claims 1-6, 8-10, 47 and 48 are pending in this application. Claims 47 and 48 are canceled herein without prejudice. Claims 1-5 and 8-10 are amended herein for clarity to more particularly define the invention. Support for these amendments is found in the language of the original claims and throughout the specification. No new matter is added by these amendments and their entry and allowance are respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

Rejection under 35 U.S.C. § 112, first paragraph

The Office Action states that claims 1-6, 8-10, 47 and 48 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

Claim 1 as presented herein recites a method of identifying a human subject having an increased risk of developing breast cancer or colon cancer, comprising detecting upregulation of the *CLN3* gene in said subject, wherein upregulation of the *CLN3* gene in said subject identifies the subject as having an increased risk of developing breast cancer or colon cancer. Pending claims 2-6 and 8-10 depend from claim 1 and claims 47-48 are canceled herein without prejudice, the subject matter therein having been incorporated into claim 1.

The methods of claim 1 and of claims dependent therefrom are adequately enabled by the teachings of the instant specification. In particular, claim 1 recites a method for the identification of a human subject having an increased risk of developing breast cancer or colon cancer on the basis of detection of upregulation of the *CLN3* gene in the subject. The claim does not recite a method for diagnosis or prognosis of a subject; claim 1 only recites a method whereby the subject is identified as having an increased risk of these two particular cancers. The detection of upregulation of the *CLN3* gene in a subject is carried out according to methods well known in the art and would be well recognized by one of ordinary skill in the art not to require undue experimentation. The method of

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claim 1 is enabled by data provided in the specification in Example 2 (pages 25-28) demonstrating the detection, by the inventors, of the upregulation of *CLN3* in three separate breast cancer cell lines and the upregulation of *CLN3* in three separate colon cancer cell lines. The inventors further established a correlation between upregulation of the *CLN3* gene and colon cancer by demonstrating upregulation of the *CLN3* gene in 8 of 10 solid tumors as compared with corresponding normal colon tissue (Ryolva et al.; page 804, bridging paragraph and Figure 4). These findings clearly enable a method of identifying a human subject as having an increased risk of developing breast cancer or colon cancer by detecting upregulation of the *CLN3* gene in the subject.

Although the information set forth above adequately addresses the enablement rejection, applicants also comment on the Examiner's statements that the basis for her rejection of the claimed invention for lack of enablement is due to the alleged inability to use tumor cell lines for predicting an increased risk of developing a particular cancer. In support of this position, the Examiner cites Chabert et al., which describes studies wherein the level of expression of poly(ADP-ribose)polymerase gene is compared in three tumor cell lines (a mastocytoma, a lymphoma and a glioma cell line), and in tumors grown artificially *in vivo* from these cell lines. This paper discloses nothing more than the activity of a single gene, which is not the *CLN3* gene, in cancer cell lines that are not breast cancer or colon cancer cell lines. Therefore, a person of skill in the art reading this paper would not reasonably conclude or even assume anything about the "applicability of cell-culture results to *in vivo* situations" (Chabert et al. abstract) for any gene other than the poly(ADP-ribose)polymerase gene and it is not apparent that one of skill in the art could even conclude anything about the poly(ADP-ribose)polymerase gene, based on studies that compare cell lines with artificial tumors produced from cell lines.

Furthermore, the Examiner relies on an editorial article authored by Mr. Gerald B. Dermer, who is identified as a former cancer researcher, but for whom no other credentials are provided that establish Mr. Dermer as one of appropriate skill in the art to speak to the issue of correlating increased risk of developing breast cancer or colon cancer with upregulation of the *CLN3* gene in a

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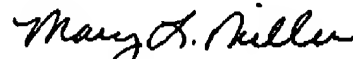
human subject. In fact, the article by Mr. Dermer, which was published in *Bio/Technology* in 1994, includes the disclaimer that the views expressed are the author's own. Further analysis of Mr. Dermer's article reveals that Mr. Dermer's opinions regarding cell culture and cancer research are unsupported by reference to any data, published studies or other evidence to validate his opinion. Thus, this opinion piece provides no basis whatsoever for one of skill in the art to reasonably conclude anything regarding the "applicability of cell-culture results to *in vivo* situations."

For these reasons, the invention as claimed herein would not require undue experimentation and the Examiner has failed to provide valid evidence that the claimed methods lack enablement. Thus, this rejection has been overcome and applicants respectfully request its withdrawal.

Applicants request the opportunity to discuss this application with Examiner Goldberg and her Supervisory Examiner Gary Jones over the telephone before any further official actions are issued for this application.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of \$1475.00 (\$1080 as fee for a five month extension of time pursuant to the filing of a Notice of Appeal on April 25, 2005 and \$395.00 fee for Request for Continued Examination.). This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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CERTIFICATE OF FACSIMILE TRANSMISSION

Date of Deposit: November 23, 2005

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office on the date indicated above via facsimile number 571-273-8300 and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Tracy Wallace